APPLICATION

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TITLE: SURGICAL SUTURE PLACEMENT DEVICE

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SURGICAL SUTURE PLACEMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority from U.S. Provisional Patent Application Serial No. 60/394,131, filed July 3, 2002, the subject matter of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

This invention relates to devices and methods for performing anastomoses.

BACKGROUND

Over 100,000 radical prostatectomies are performed each year. The vast majority of these procedures are performed using an open surgical technique, despite proven advantages of the laparoscopic radical prostatectomy including improved visualization, substantially reduced blood loss, and reduced patient morbidity. The most technically challenging step of the laparoscopic technique is the urethrovesical anastomosis. The technical difficulty of this anastomosis serves as a major barrier to broader-scale use of laparoscopy to perform the radical prostatectomy.

SUMMARY

The invention includes devices and methods for placing a suture to connect two tissues, e.g., two tubular tissues. For example, the device can be used to connect the urethra to the bladder neck to perform an urethrovesical anastomosis, e.g., after removal of the prostate. The anastomosis consists of reattachment of the urethra to a larger diameter opening in the bladder neck. The invention can also be used to perform anastomoses in other vessels and lumens and for difficult open prostatectomies.

In one aspect, the invention features a surgical suture placement device that includes a handle assembly, which can optionally rotate; an elongated hollow outer tube connected at a proximal end to the handle assembly; a suturing assembly rotatably

secured to a distal end of the elongated hollow outer tube; and a hollow inner tube, e.g., a flexible tube, located within the hollow outer tube and connecting the handle assembly to the suture assembly by traversing the inside of the elongated hollow outer tube.

In this device, the suturing assembly can include a holding member for removably holding a needle. The device can also include the needle itself, wherein the needle is hollow and has an open, sharp-tipped distal end, e.g., with rounded edges that avoid damage to the suture material that passes through the needle. The hollow needle can be configured to enable a suture to pass through a portion of the needle, the suture extending from an aperture on a surface at a proximal end of the needle to an opening at a sharpened distal end of the needle.

The surgical suture placement device can further include a thin flexible rod arranged within the hollow inner tube, wherein the rod is connected at a proximal end to the handle assembly and has a distal end configured for connection to a needle located within the suturing assembly. The surgical suture placement device can also include a needle plunger arranged within the handle, wherein a distal end of the needle plunger attaches to a proximal end of a needle by means of a thin rod, wherein the thin rod traverses the interior of the flexible hollow tube.

The surgical suture placement device can also include a spring that biases the needle plunger into an extended position and the needle into a retracted position. In addition, the suturing assembly can be angled away from a longitudinal axis of the elongated hollow outer tube, e.g., a longitudinal axis of the suture assembly can be at an angle of 45° to a longitudinal axis of the elongated hollow outer tube.

In certain embodiments in which the handle rotates, rotating the handle concurrently rotates the hollow inner tube and the suture assembly as a unit.

The suture assembly of the new device can include a needle cover attached to the elongated hollow outer tube; a needle guide with a suture aperture attached to the needle cover; and a suture holder attached to the needle guide, wherein the needle guide is secured between the needle cover and the suture holder.

In another aspect, the invention features methods of suturing a first tissue to a second tissue by obtaining a new suture placement device as described herein and loading

the device with a needle and suture. Then one moves a distal portion of the suture placement device into proximity of tissue to be sutured; positions the suturing assembly at a proper angle; extends a suture needle through a portion of a first tissue; retracts the needle leaving a first loop of suture extending from the first tissue; extends the needle through a portion of a second tissue; retracts the needle leaving a second loop of suture extending from the second tissue; and connects the first and second loop of suture to suture the first tissue to the second tissue.

In these methods, the first and second loops of suture can be connected with a knot or with a crimping device. The method can be a surgical anastomosis, and the anastomosis can be performed during a tubal ligation, heart bypass surgery, coronary artery bypass graft, or urethrovesical anastomosis. In these methods, the suture placement device need not be removed from the proximity of the tissue until suturing is complete. The first and second tissues can be different (e.g., the urethra and the bladder neck), or they can be different sections of the same tissue. In certain methods, the tissue to be sutured can be adjacent to a body cavity (e.g., the bladder), the suture placement device is inserted into the body cavity, and then is not removed from the body cavity until the suturing is complete.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic cross-section of a suture placement device.

FIGs. 2a and 2b are schematic diagrams of a protracted and extended needle, respectively, in a rotating suture assembly of a suture placement device.

FIGs. 3a to 3c are schematic diagrams of a protracting needle used in a new suture placement device.

FIG. 4 is a schematic diagram of a hollow needle.

FIG. 5 is a disassembled view of a rotating suture assembly.

FIGs. 6a and 6b are schematic diagrams of how a suture knot is formed using the new suture placement device.

DETAILED DESCRIPTION

The invention greatly reduces the technical expertise required for performing laparoscopic radical prostatectomies. The invention enables more surgeons to take advantage of the proven advantages of laparoscopic techniques. Typically, six to ten stitches are used for an anastomosis. Each stitch requires placing suture material through the urethra and bladder neck, approximating the two structures, and securing the ends of the suture, typically by tying a knot. Thus, placement of each stitch can be considered in two steps: (1) placement of suture material through a first tissue and a second tissue, and (2) securing the ends of the suture, such as with a knot. The invention disclosed herein assists in the first step, placement of suture material though the urethra and bladder neck. This step currently requires very sophisticated laparoscopic skills and is not feasible for most urologists. Products are presently available to assist in the second step. These devices can use a crimp to secure the ends of the suture. Such devices are described, e.g., in U.S. Patents Nos. 5,931,844, 6,086,608 and 6,200,329.

FIG. 1 shows a surgical suture placement apparatus, designated generally by **10**, for assisting in an anastomosis, e.g., an urethrovesical anastomosis. The device has the general shape of a urethral sound that is a device commonly used by urologists. The device includes an elongated hollow outer tube **14,** which has a predetermined diameter, e.g., about a 24 French (0.301 in) diameter, a handle assembly **12,** and a rotating suturing assembly **16**. The device also includes a needle plunger **22** and a needle **20** (shown

partially extended). The needle plunger is spring loaded **26** so that the needle **20** is normally in the fully retracted position.

The surgical suture placement device **10** has a handle assembly **12** rotatably connected to the proximal end of the elongated hollow outer tube **14**. The elongated hollow outer tube **14** is rigidly attached to a sleeve **15** at the proximal end **14a**. The handle assembly **12** rotates within the sleeve **15** to provide rotation to the rotating suturing assembly. Sleeve **15** is cylindrical in shape with a diameter greater than the diameter of the elongated hollow outer tube **14**.

The rotating suturing assembly **16** is rotatably attached to the distal end **14b** of the elongated hollow outer tube **14**. A hollow inner tube **28** having an outer diameter smaller than the inner diameter of the elongated hollow outer tube **14**, traverses the elongated hollow outer tube **14** internally to make a second connection between the handle assembly **12** and the suturing assembly **16**. The second connection between the handle assembly **12** and the suturing assembly **16** is a nonrotatable connection. Thus, turning the handle **12** turns the suturing assembly **16** in the same direction. As shown in FIGs. 2a and 2b, hollow inner tube 28 can include ridges to allow the tube to flex yet maintain rotational rigidity.

The connections discussed above can be made by a variety of methods, e.g., fitted sleeves, clamping, mated male and female threads, soldering, gluing, or a gear assembly.

The suturing assembly **16** includes a holding member **18** which is rotatably connected to the elongated hollow outer tube **14**. The holding member **18** (also shown in section) holds a suturing needle **20**. The holding member **18** includes a narrow opening **18a** which traverses one side of the holding member **18** and allows for protrusion of the needle **20** from the holding member **18** during suturing. The needle **20** protrudes from the holding member **18** at a set angle to the longitudinal axis of the holding member. The angle can be, for e.g., 30°-75°.

In another variation of the invention, the holding member **18** includes markings **18b** that are used to position the holding member **18** at the proper angle and insertion depth in the subject. The markings **18b** are etched or otherwise placed during manufacturing on to the holding member **18** and are viewed through a laparoscopic

opening in the subject's abdomen. During suture placement through the urethra, most of the rotating suturing assembly **16** is inside the urethra and the location of the opening **18a** is not visible; thus, markings **18b** are needed to indicate the angle that the needle **20** will be deployed and to provide an approximate location of the needle **20** to the urethra opening.

The needle **20** is connected to the spring-loaded plunger **22**, which extends through the handle assembly **12**, by e.g., a thin rod **31**, which connects to the distal end of the plunger **22** and the proximal end of the needle **20**. Pressure exerted downward on the plunger **22** forces it into the handle assembly, causing a force to be exerted on the thin rod **31**, which in turn exerts a force on the needle **20**, resulting in the needle **20** protracting from the holding member **18** through the narrow opening **18a**. In the absence of a force, the spring **26** is selected and arranged to maintain the plunger **22** in an extended position and the needle **20** in a retracted position within the holding member **18**.

The handle assembly **12** can rotate in a clockwise or counter-clockwise direction. In one variation of the invention, rotation of the handle assembly **12** concurrently rotates the connected hollow inner tube **28**, while the elongated hollow outer tube **14** remains stationary. This movement also rotates the holding member **18**, which is securely connected to the hollow inner tube **28**, in the same direction.

The distal end **14b** of the elongated hollow outer tube **14** can be angled away from the central axis of the outer tube **14**. The angle **24** occurs prior to the junction **19** of the elongated hollow outer tube **14** with the holding member **18**. The bend of the elongated hollow outer tube **14** is selected for the specific surgery, e.g., a 45° angle from the longitudinal axis of the elongated hollow outer tube **14**. The elongated hollow outer tube **14** is made of a rigid material to maintain the angle **24**, and also to allow the device **10** to be placed into a subject without distorting the structure of the device **10**. The outer tube **14** can be manufactured of, e.g., stainless steel or other metals, and plastic polymers.

When the elongated hollow outer tube **14** is angled, the hollow inner tube **28** and the thin rod **31** must be bendable at their distal ends. During assembly, the hollow inner tube **28** is inserted into the elongated hollow outer tube **14**, and the thin rod **31** is inserted into the hollow inner tube **28**, resulting in both components assuming the shape of the

elongated hollow outer tube **14**. The hollow inner tube **28** must be sufficiently flexible (e.g., it can be made of plastic, a spring, fiberglass, biopolymers, or rubber) to assume the angle of the elongated hollow outer tube **14**, but have sufficient rotational rigidity to rotate the holding member **18**. The thin rod **31** must also have the flexibility (and thus can be manufactured of, e.g., plastic, a spring, fiberglass, a biopolymer, or rubber) to assume the angle **24** of the elongated hollow outer tube **14**, but have the longitudinal rigidity to transfer a protraction force from the spring-loaded plunger **22** to the needle **20**.

A variation of the invention is that the distal end of the elongated hollow outer tube **14** is not angled from its longitudinal axis, but remains straight.

FIGs. 2a and 2b are schematic cross-sectional views of the suture assembly **16** connected to a portion of an elongated hollow outer tube **14**, a hollow inner tube **28**, and a rod **31**. FIG. 2a shows the needle **20** in a recessed position (with only suture material **33a** extending out of the device). The suture assembly **16** contains a spool **33** of suture material **33a** that is threaded through the interior of the hollow needle **20**. Applying pressure to the spring loaded **26** plunger **22** forces the rod **31** to extend the connected needle **20** through the narrow opening **18a** in the holding member **18**, and out of the device as diagramed in FIG. 2b.

Referring to FIG. 3a, the needle **20** can be extended from the holding member **18** by a variety of methods. In the variation shown in FIG. 3a, the needle **20** has a curved, banana shape, and is made of a rigid material, e.g., stainless steel or other metals, a plastic, or a polymer. The thin rod **31** extends through the angled elongated hollow outer tube **14** and pushes the needle **20** outward and at an angle from the holding member **18**. The hollow inner tube **28** is not shown in this drawing.

FIG. 3b shows another embodiment in which the needle **20** is straight and is made of a rigid material. The thin rod **31** pushes the needle **20** through a straight hollow guide **17**, to protract out of and at an angle to the holding member **18**. The hollow inner tube **28** is not shown in this drawing.

FIG. 3c shows another embodiment in which the needle **20** is made of a material rigid enough to penetrate tissue, but flexible enough to adapt to a curved, hollow guide **29**. The thin rod **31** pushes the needle **20** through the curved guide **29** and out of the

narrow opening **18a** at an angle to the holding member **18**. Again, the hollow outer tube **28** is not shown in this drawing.

FIG. 4 shows needle **20** of the rotating suturing assembly **16**. The needle is hollow with open proximal **38** and distal **36** ends. In use, the proximal end **38** is connected to the distal end of the thin rod **31**. The surface near the proximal end **38** of the needle **20** has an aperture **34**, with rounded edges **34a**, traversing the outer to the inner surface. This aperture **34** is where the suture material **33a** enters the needle **20**; the rounded edges **34a** protect the suture material from damage. The distal end **36** of the needle **20** contains the sharp, pointed end **30** of the needle, which allows the needle **20** to smoothly traverse a tissue. The edges **32** are also rounded, preventing damage to the suture. The suturing material extends through the hollow needle **20** and exits through the distal end **36**. In this variation of the invention, the needle **20** is slightly curved.

FIG. 5 is a disassembled view of the rotating suturing assembly **16**. The bottom part shown in the figure is the needle cover **42** with an attached elongated hollow inner tube **28** which can rotate inside the hollow tube **14** to provide rotation to rotating suturing assembly **16**. The middle part shown in the figure is the needle guide **44**, which contains and guides the needle **20** through the slotted groove **45.** The needle guide also has a suture hole **46** for the suture material to extend from the suture holder **48** (top part shown in the figure) to the hollow needle **20**. Thirty inches or more of suture material can be loaded in a spool **33** or in figure-eight configuration in the suture holder **48** for deployment through the needle guide hole **46** into the needle **20**. The suture material then extends through the hollow needle **20** to the sharp-edge end **30** of the needle **20** where a short length of suture material is deployed. Pin **49** holds the various parts together.

All components of the suture placement device can be manufactured by methods known in the art. All components of the device can be made reusable, therefore, each component can be sterilized without damage to the component, e.g., UV irradiation, autoclaving, exposure to alcohol. Alternatively, all components of the device can be made disposable and replaceable.

Methods of Use

FIGs. 6a and 6b show the general use of the suturing placement device **10** to place a suture during an anastomosis. FIG. 6a shows the placement of the suture before crimping. The tissues to be connected, **50a** and **50b**, have been pierced by the needle **20** leaving a loop of suturing material **33a**, which is fed from a spool **33** of suturing material, extending through the tissue wall. A laparoscopic instrument **60** makes a single cut through the looped suturing material **33a** severing it from the needle. In FIG. 6b, each loop of the severed suturing material **33a** that extends through each tissue wall **50a** and **50b** has been entertwined by a laparoscopic instrument **60** (not shown in FIG. 6b) to form a knot. Alternatively, the cut ends can be crimped using standard techniques and devices.

One specific use of the suture placement device **10** is for placing suturing material through a urethra and a bladder neck after radical prostatectomy. The device **10** can be inserted into the penis and extended to the site of anastomosis through the transected proximal urethra after the prostate has been removed. Placing the device **10** in the urethra provides stability to the device **10** and places the device **10** in close proximity to the site of anastomosis. Inserting the device **10** through the penis also allows unhindered use of the laparoscopic instruments during the anastomotic procedure to manipulate tissue or suture material as necessary. Markers **18b** on the suturing assembly **16** are viewed with a laparoscope and are used to position the suturing assembly **16** in the urethra at the proper angle and insertion depth. Once the appropriate position is achieved, the needle plunger **22** is pressed to extend the needle **20** with suturing material to push through the wall of the urethra.

The needle **20** is then retracted by reducing force on the spring-loaded needle plunger **22**, leaving a length of suturing material extending from the outside of the urethra. This length of suturing material is then pulled using a laparoscopic instrument to obtain an appropriate length of suturing material for the stitch. The device **10** is then positioned inside the bladder neck. Again, the needle **20** is extended through the bladder wall and retracted, leaving a length of suturing material extending from the outside of the bladder neck. The suture can be then cut (when an interrupted anastomosis is desired), the ends of the suture are pulled to approximate the urethra and bladder neck, and the

suturing material ends are secured using a knot or a crimping device. The rotating suturing assembly **16** is then positioned at a different location and the process is repeated to apply the second suture. The surgeon can repeat the process to apply as many sutures as desired, and the sutures are applied without removing the device from the penis. Alternatively, a "running" anastomosis can be performed where the suture is not cut until the stitching is completed. As another alternative, a "tennis racquet" anastomosis, which is well known to those skilled in the art, can be performed by attaching the urethra to a short circumference of bladder neck and then suturing bladder neck to bladder neck. Other anastomosis alternatives can be achieved using the new device as the surgeon desires.

The suture placement device **10** can be used in many other locations within the body, essentially in any situation where a tube needs to be connected to a larger tube or a larger lumen (e.g., blood vessel to blood vessel, blood vessel to organ, bowel to bowel). A similar device can be used to connect a tube to a larger tube outside the body as well. In addition, the new device can be used to deliver a cytotoxin or radiolabel to a site (e.g., a tumor) by placing the compound into the rotating suture assembly and delivering the compound instead of, or at the same time as, delivering the suture.

OTHER EMBODIMENTS

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the following claims.